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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORTHO BIOTECH PRODUCTS, L.P., Plaintiff, v. AMGEN INC. and AMGEN USA INC., Defendants.	**Civil Action No. 05-4850 (SRC-MF)** **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Ortho Biotech Products, L.P. ("Ortho"), a New Jersey limited partnership with its principal place of business located at 430 Route 22 East, Bridgewater, NJ 08807, upon knowledge with respect to its own acts and upon information and belief with respect to all other matters, alleges by way of this Amended Complaint against Defendants Amgen Inc. and Amgen USA Inc., Delaware corporations with their principal places of business at One Amgen Center Drive, Thousand Oaks, CA 91320, (collectively, "Amgen"), as follows:

SUMMARY OF CLAIMS

1. This antitrust action, brought under Sections 1 and 2 of the Sherman Act, involves an anti-competitive tying arrangement and pricing scheme implemented by Amgen in the oncology clinic market. The scheme ties substantial purchases of Amgen's Red Blood Cell

Growth Factor ("RBCGF") drug to its dominant White Blood Cell Growth Factor ("WBCGF") drugs. Both WBCGF and RBCGF drugs are needed by oncology clinics to treat cancer patients. The purpose of Amgen's scheme was and is to monopolize the market for sales of RBCGF drugs to oncology clinics. The result has been, and will continue to be, less price competition, less physician and patient choice and an increased expense to the public health system.

2. Ortho sells Procrit®. Amgen sells Aranesp®. Both are RBCGF drugs that, prior to the implementation of Amgen's scheme, competed head-to-head in a two-player market. Annual combined sales to oncology clinics of these two products exceeded $2.8 billion in 2005.

3. Amgen also sells Neulasta® and Neupogen®, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs. Ortho does not sell a WBCGF drug.

4. Amgen's illegal pricing scheme penalizes oncology clinics on purchases of its monopoly WBCGF drugs if the clinics do not purchase significant volumes of its Aranesp instead of Procrit. From its inception in April 2004 through to October 2005, the illegal pricing scheme caused Aranesp share to increase by 46%, to approximately 66% of the oncology clinic RBCGF drug market.

5. On October 1, 2005, Amgen's pricing scheme became considerably more coercive. Amgen imposed, and continues to impose, even steeper pricing penalties on Amgen's monopoly WBCGF drugs when oncology clinics do not purchase 75% or more of their RBCGF drugs from Amgen. In fact, for a clinic to receive the same level of RBCGF and WBCGF drug rebates it received under the pre-October 1, 2005 contract, it had to increase its Aranesp share well above that amount.

6. Amgen's pricing scheme has reached the point where, for a substantial percentage of its patients, an oncology clinic is put in a completely untenable position. A clinic will end up losing several hundred dollars per administration of Amgen's leading WBCGF drug because the cost of buying the drug (absent the contractual rebates) vastly exceeds the amount of government reimbursement. The clinic can only gain access to the rebates on Amgen's monopoly WBCGF drugs when they purchase virtually all of their RBCGF drug requirements from Amgen.

7. Defendants' conduct constitutes a tying arrangement in violation of Section 1 of the Sherman Act under either a *per se* or Rule of Reason analysis. As the result of Amgen's monopoly power in the sale of WBCGF drugs to oncology clinics, Amgen's pricing scheme leaves oncology clinics with no economic alternative but to purchase virtually all RBCGF drugs from Amgen. Moreover, WBCGF and RBCGF drugs are distinct and separate products and a not insubstantial amount of commerce is involved.

8. Amgen's actions also violate Section 2 of the Sherman Act. The purpose of Amgen's anticompetitive pricing scheme is to monopolize the oncology clinic market for RBCGF drugs in the United States in which Procrit is Amgen's only competitor. When it implemented the latest version of its pricing scheme on October 1, 2005, there was a dangerous probability that, by engaging in this exclusionary conduct, Amgen would succeed in its monopolistic plans. By the continued imposition of that scheme, Amgen has succeeded in maintaining a monopoly in the RBCGF clinic market.

9. The anticompetitive conduct at issue here has harmed Ortho and is not in the public interest. Procrit's ability to price compete in the oncology clinic market for RBCGF drugs has largely ceased. Since Procrit was introduced in 1991, it has been used to treat

millions of patients who suffer from chemotherapy-induced anemia ("chemo-induced anemia"). Procrit was the first RBCGF drug on the market and it improved the lives of millions of patients. Ortho was viewed by thought leaders in the oncology market as one of the pioneers in addressing the needs of cancer patients undergoing chemotherapy. As a result, Ortho had established longstanding relationships with oncology clinics and had built-up enormous goodwill in the Procrit brand. Amgen's coercive pricing scheme has impaired and eroded that goodwill.

10. Moreover, denying clinics and ultimately patients access to Procrit is not in the public interest and has and will continue to harm consumers. Physicians should not face economic coercion, and the healthcare system should not bear the increased costs of that coercion. Forcing oncologists to abandon the lower cost Procrit as the only economically viable way to gain access to another potentially life saving drug, is not, by any measure, in the public interest.

11. For these reasons and to remedy the injuries that will be caused and have been caused by Amgen's anticompetitive conduct, Ortho seeks a permanent injunction as well as treble damages.

JURISDICTION AND VENUE

12. This Amended Complaint is filed under Section 16 of the Clayton Act, 15 U.S.C. § 26, to prevent and restrain violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1 and 2, and for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15. This Court has jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202.

13. Defendants transact business and are found in this district. Substantial interstate trade and commerce are involved and affected by the alleged violations of antitrust law that occurs within this district. The acts complained of have had, and will have, substantial anticompetitive effects in this district. Venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22 and 26, particularly as plaintiff Ortho resides here.

THE PARTIES

14. Plaintiff Ortho is a limited partnership organized and existing under the laws of New Jersey with its principal place of business located in Bridgewater, New Jersey. Ortho is one of the Johnson & Johnson family of companies. Johnson & Johnson is a corporation with its principal place of business in New Brunswick, New Jersey. Ortho sells Procrit, the drug that is the target of Amgen's monopolistic schemes.

15. Defendants Amgen Inc. and Amgen USA Inc. are corporations organized and existing under the laws of Delaware with their principal places of business in Thousand Oaks, California. Amgen, among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta.

FACTUAL ALLEGATIONS

A. Ortho and Amgen are the Only Competitors in the Sale of RBCGF Drugs to Oncology Clinics.

Procrit

16. Severe anemia is most commonly seen in patients (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.

17. Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.

18. Ortho sells Procrit®, a branded version of epoetin alfa. By the Product License Agreement ("PLA") executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen's patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except anemia in patients undergoing dialysis for end stage renal disease ("ESRD"). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen®.

19. At the time of the PLA, the use of epoetin alfa to combat dialysis-induced anemia offered the greatest possibility for commercial success. However, there was no firm basis for predicting the viability of using epoetin alfa to treat anemia resulting from other disease

states. Through costly research and clinical trials, Ortho demonstrated the efficacy of epoetin alfa to treat and reduce the need for transfusions in patients undergoing treatment for other diseases. Based upon this work, Ortho secured FDA approvals, beginning in 1991, to market Procrit for the treatment of persons who develop anemia as a consequence of (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

20. Since Procrit was launched in 1991, it has been prescribed to millions who suffer from anemia included in the four indications listed above and became the standard of care for the treatment of chemo-induced anemia. As a result of Procrit's success, Ortho has paid Amgen over $1.5 billion in royalties on Procrit sales.

Aranesp

21. Amgen decided to circumvent the market exclusivity it had granted to Ortho to sell epoeitin alfa for all purposes other than dialysis. The result was Amgen's introduction of Aranesp, a synthetic form of erythropoietin known as darbepoetin alfa. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.

22. Ortho's work and investment in Procrit, which demonstrated that RBCGF drugs could be safely, effectively and widely used to combat chemo-induced anemia, helped Amgen to secure FDA approval of Aranesp and to sell Aranesp into markets in which physicians had been educated by Ortho about the benefits of RBCGF drugs.

23. Given the scope of Amgen's patents, Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales to oncology clinics for Procrit and Aranesp exceeded $2.8 billion in 2005.

B. Amgen Has a Monopoly on the Sale WBCGF Drugs.

24. Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a white blood cell deficiency that is potentially life threatening. Neutropenia is a side effect of chemotherapy which potentially compromises a patient's immune system. The disease occurs not only in many patients undergoing chemotherapy, but in individuals suffering from a number of other diseases.

25. Ortho does not sell a WBCGF drug, but Amgen does. Amgen sells two WBCGF drugs, Neupogen® and Neulasta®. The only other WBCGF drug sold is Leukine®, which is distributed by Berlex Laboratories.

26. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product, which has been modified so that, according to Amgen, one injection of Neulasta is roughly equal to 7 injections of Neupogen.

27. Amgen dominates the sales of WBCGF drugs which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales. Unlike Amgen's WBCGF drugs which are administered by subcutaneous injection, Leukine must be administered intravenously – a longer and more costly process.

C. Amgen has Monopolized the Sales of RBCGF Drugs to Oncology Clinics by Leveraging its WBCGF Drug Monopoly.

1. Amgen Begins Bundled Pricing on Aranesp and its WBCGF Monopoly Drugs.

28. Virtually all oncology clinics administer both RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, these clinics must buy WBCGF drugs, particularly Neulasta, from Amgen.

29. This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Amgen's strategy for selling Aranesp has been to penalize a clinic on the pricing of its dominant WBCGF drugs if the clinic did not purchase substantial amounts of Aranesp. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to reduce Procrit's share of clinic sales by means other than competition on the price of RBCGF drugs or their relative merits.

2. The Early 2004 Amgen Contract.

30. Amgen implemented the coercive pricing scheme at issue in the spring of 2004. At that time, Amgen began offering substantial "rebates" to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract ("APC").

31. Amgen's pricing to oncology clinics under its APCs are broken into three groups – large, medium and small accounts – based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that, once reached, allow the clinic to earn a specified level of rebate. The dollar volume targets Amgen puts in each clinic's APC represent a specific percentage requirement of

market share based on that clinic's historical usage. Rebates are earned when Amgen's share of the clinic's estimated total APC purchases reach those levels.

32. For example, under the APCs in effect in the first half of 2004, a large account oncology clinic which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen received significantly greater rebates – a 25% rebate on its Aranesp purchases and a 25% rebate on Amgen's WBCGF drug purchases. An oncology clinic that did not meet its APCs volume requirements would only receive a minimal rebate or discount. (Examples of the rebate levels for APCs during this time frame are attached as Attachment A.)

3. **The January 1, 2005 Amgen Contract.**

33. Effective January 1, 2005, Amgen modified its APCs. Amgen apparently recognized that simply providing an oncology clinic with a combined dollar volume target might give the clinic the flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target, rather than shifting its Procrit purchases to Aranesp. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced oncology clinics to purchase more Aranesp, which was not subject to any incentive restrictions to reach higher rebate levels.

34. Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered to oncology clinics, further penalizing those

oncology clinics that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp.

35. Under the revised APC, a large oncology clinic that purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive a 30% rebate on its Aranesp purchases and a 25% rebate on its WBCGF drug purchases. (Examples of the rebate levels for APCs during this time frame are attached as Attachment B.)

36. All of these changes forced a clinic to buy less Procrit and more Aranesp in order for the clinic to get access to both the WBCGF and RBCGF rebates.

37. As a result of these pricing schemes, Ortho's share of sales to oncology clinics dropped precipitously. In the first quarter of 2004, Ortho had a 55% share of the oncology clinic market for RBCGF drugs and Amgen had a 45% share. By October 2005, Ortho's share had dropped to approximately 34%, with Aranesp having a 66% share.

38. This significant shift in relative market share was attributable to oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order for these customers to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen.

39. The effect of Amgen's coercive tying arrangements on sales of RBCGF drugs to oncology clinics is evidenced by comparing Procrit and Aranesp market shares to

oncology clinics with their respective share of sales in another market – sales to retail drug stores – where Amgen has not introduced these tying arrangements. As a result, Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs. Procrit's share of sales to retail drug stores was, and remains at, approximately 70%.

D. Amgen's New Pricing Scheme is Designed to Eliminate Procrit from the Oncology Clinic Market.

40. Having gained a 65% share of sales to oncology clinics by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen then tightened its squeeze on this market. On October 1, 2005, Amgen's pricing scheme became significantly more coercive.

41. As with the previous pricing schemes, each clinic was given a series of levels of dollar volume targets for its total Amgen purchases of RBCGF and WBCGF drugs, as illustrated below for a large account.[1] The higher the Amgen gross purchases, the higher level of rebate an oncology clinic could achieve:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%
1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

42. However, to gain access to even the lowest rebate level described above an oncology clinic was required to meet separate Aranesp and Neulasta dollar

[1] Examples for medium and small accounts are set forth in Attachment C.

volume triggers. The threshold for Aranesp was set at dollar amounts equal to 65% of a clinic's prior RBCGF drugs purchases (i.e., a 65% market share requirement), while the threshold for Neupogen and Neulasta was set at up to 100% of a clinic's prior purchases. Thus, to earn the minimum rebates required to avoid a loss on the administration of the WBCGF drugs to Medicare patients, a clinic has to buy Aranesp for at least 65% of its total RBCGF purchases.

43. A higher initial dollar volume threshold for Aranesp was only the start of the October 2005 pricing scheme. The scheme also was intended to coerce oncology clinics to purchase Aranesp for more than the minimum market share requirements. Under the modified APCs, for an oncology clinic to receive the same aggregate value it had been receiving while performing under the pre-October 1, 2005 APC (described above), each clinic was required to purchase larger volumes of Aranesp in order to reach the higher levels of the rebate schedules. Moreover, the clinic's Aranesp purchases had to amount to at least 75% of its total RBCGF drug purchases to be eligible for the same level of rebates previously received. For example, for a large clinic, the top Aranesp rebate was 26%. This was 4% less than under the previous Amgen bundle, where a clinic could receive a 30% rebate. However, the clinic can earn back the additional 4% by taking its Aranesp share up to 75%. Thus, the 2005 pricing scheme was and is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate.

44. This pricing scheme also reduced the highest Neulasta rebate from 25% to 21% for large clinics. As with the Aranesp rebates, an oncology clinic can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases were of Amgen's Neulasta and the higher threshold for Amgen's Aranesp (up to 90%) was met.

45. The October 2005 pricing scheme continued to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC did not place caps on Aranesp. This further drove oncology clinics to purchase all or substantially all of their RBCGF drugs from Amgen.

46. A clinic that did not meet its Aranesp volume requirement would only receive a 4% rebate on Neulasta. Previously, an oncology clinic that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is being penalized an additional 3.1% to 5.5% on its Neulasta purchases under the October 2005 APC.

E. The Impact of this Pricing Scheme on an Oncology Clinic's Medicare Business.

47. Failing to meet the minimum Aranesp purchase requirements in the revised APCs has severe economic consequences on oncology clinics. Because the use of WBCGF drugs is the standard of care to treat neutropenia, oncology clinics have no choice but to carry Neulasta.

48. Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula, an oncology clinic would have to pay Amgen hundreds of dollars more on each treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients.

49. On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The formula is based on the drugs' average selling price ("ASP") plus 6%. Thus, if a

clinic bought a drug that had an ASP of $1,000, the clinic would be reimbursed $1,060. This reimbursement amount is static regardless of what the particular clinic actually paid for the drug. The "plus 6%" is not intended to be profit to an oncology clinic. It is to provide the clinic with some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays.

50. As the term suggests, the ASP of a drug is an average based on the prices paid – and discounts and rebates earned – by all purchasers of such drugs. Accordingly, a Medicare provider that does not, or can not, avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug.

51. Unless an oncology clinic qualifies for Amgen's rebates, this is precisely the situation the clinic will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is $2,603.00. The Medicare reimbursement (i.e., ASP plus 6%) per unit of Neulasta was $2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or $524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, the clinic had to receive rebates and discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their modified APCs. In other words, unless the clinics meet the Aranesp

volume requirements, the clinic will pay Amgen $295.87 more per administration of Neulasta than the clinic is being reimbursed by the government.

52. The foregoing example is based on Neulasta's list price as of October 2005. Amgen has since increased the list price of Neulasta, which would result in oncology clinics losing even more money if they fail to meet Amgen's purchase requirements.

53. Amgen's latest pricing scheme has forced and will force oncology clinics to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp, which translate into substantial market share requirements. This creates a strong incentive on the part of the oncology clinic to stock only Aranesp, or to reduce dramatically the level of Procrit stocked. Few oncology clinics are able to bear the cost and financial risk of also stocking Procrit given the level of Amgen's dollar volume requirements for Aranesp. An oncology clinic that wanted to use even a small amount of Procrit would need to stock both Procrit and Aranesp but would have to carefully manage and monitor relative usage of Aranesp and Procrit, with severe financial consequences should it err in this process. Most oncology clinics are in no position to take such risks.

54. Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing oncology clinics that do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime, preclude Ortho from competing over the long-term in the RBCGF oncology clinic market. Ortho understands that one Amgen official already has boasted to a Procrit customer that they expect 75% of existing Procrit customers will agree to Amgen's latest pricing scheme. Amgen had

secured nearly 65% of RBCGF drug sales in the oncology clinic market before implementing its latest version of the APC. Amgen's coercive revisions have enabled it increase and maintain its monopoly share in the RBCGF drug oncology clinic market.

F. Ortho's Ability to Respond Competitively is Constrained by Amgen's Tying Arrangement.

55. Ortho is an equally efficient competitor, and Ortho supports price competition between rival companies as the hallmark of a free market. Ortho has been prepared and willing to engage in fair, head-to-head, price competition between Procrit and Aranesp. But given the way in which government reimbursement works for a large percentage of a clinic's patients, Amgen's scheme of tying rebates on its monopoly drug to purchases of its RBCGF drug effectively precludes Ortho from responding with commensurate price cuts. That will only result in Ortho inevitably pricing below cost and in less competition.

56. As alleged in paragraph 49, the government's reimbursement formula for Medicare patients for Procrit and Aranesp is based on each product's ASP plus 6%. Absent Amgen's tying arrangements in which WBCGF rebates are tied to Aranesp purchases, price competition between Aranesp and Procrit (in the form of discounts or rebates) would have resulted in Aranesp and Procrit each having a lower ASP as the government recalculates product ASPs. Here, the rebates provided on Neulasta, while tied by Amgen to an oncology clinic buying a certain volume of Aranesp, have not been, and will not be, considered as the Aranesp ASP is recalculated by the government. As a result, offering Neulasta rebates tied to Aranesp purchases allows Amgen to make it financially attractive to buy Aranesp, but in a way which avoids the corresponding effect of a lower Aranesp ASP (which, in turn, provides an oncology clinic with a smaller cushion, in dollar terms, on reimbursement for Aranesp, i.e., 6% of a lower ASP).

57. Put simply, by tying together rebates on WBCGF drugs with purchases of Aranesp, Amgen forces Ortho to absorb on its one product the discounts Amgen has spread over two products. The result of Ortho having to absorb discounts on its one product, Procrit, is that it will drive Procrit ASP down and, correspondingly, the level of government reimbursement on Procrit. Because, however, the WBCGF rebates are a disguised way of discounting Aranesp, the Aranesp ASP will not go down correspondingly.

58. The lack of parity in the lowering of the ASPs of Procrit and Aranesp – because of the Amgen tie – has put Ortho at an enormous disadvantage and effectively precludes price competition. If Ortho were to offer a discount on Procrit commensurate with discounts offered by Amgen on its WBCGF and RBCGF drugs, a lower ASP for Procrit would be recalculated by the government at subsequent reporting intervals. (ASPs are recalculated each quarter based on pricing data from two quarters earlier.) Procrit would then have to offer an additional discount on the lower ASP because an ASP plus 6% reimbursement on a lower ASP provides the clinic with less money to cover its costs (i.e., 6% of a lower ASP). While Ortho would be required to make up the difference in dollars to oncology clinics under a lower Procrit ASP, Amgen would not on Aranesp. Amgen's rebates are tied to its WBCGF drugs and, therefore, Amgen could match any incremental margin created by Procrit discounting with incremental incentives on its WBCGF drugs. Consequently, the Aranesp ASP would not drop to the same extent as Procrit's. The result of Procrit having a lower ASP than Aranesp is that Ortho would be forced to continue to chase Procrit's ASP down – each drop in the Procrit ASP will require an additional discount on the lower ASP to make up the dollar discount to oncology clinics to cover their costs. Meanwhile, the Aranesp ASP has remained and would remain stable because Amgen's WBCGF rebates do not affect the Aranesp ASP, although they are tied to and

driving Aranesp sales. The Procrit price spiral would result in Ortho pricing Procrit below cost in order to match Amgen's rebates on its WBCGF and RBCGF drugs.

59. On January 1, 2006, the government moved hospital reimbursement for Medicare outpatients to an ASP reimbursement system. Hospitals reportedly will be reimbursed at ASP plus 6%. The adoption of an ASP reimbursement system in hospitals allows Amgen to introduce into hospitals the same pricing scheme it is now using to foreclose price competition in the sale of RBCGF drugs to oncology clinics. Amgen may, again, simply leverage its monopoly in WBCGF drugs to provide, in effect, rebates on Aranesp without impacting the Aranesp ASP.

G. Procrit is a Highly Effective Drug.

60. Procrit was the subject of extensive clinical trials demonstrating its effectiveness in the treatment of anemia and millions of Americans have been administered Procrit over the past 14 years. Recent studies and reports continue to underscore Procrit's efficacy.

61. In May 2005, the results of a comparative clinical trial involving Aranesp and Procrit designed specifically to measure the rate of hemoglobin improvement were presented at the annual meeting of the American Society of Clinical Oncology ("ASCO"). The study authors, led by Dr. Roger Waltzman of Saint Vincent's Comprehensive Cancer Center, concluded (1) a trend toward a lower rate of transfusion in Procrit-treated patients when compared to Aranesp-treated patients, and (2) a significant difference between treatments in the total number of red blood cell units transfused, with Procrit-treated patients requiring far fewer units per patient transfused than Aranesp-treated patients.

62. Aside from the expense, time and invasive nature of the procedure, transfusions present numerous medical risks. Chemotherapy patients are significantly benefited by a reduction in the number of transfusions and the amount of blood transfused, as is the health

care system as a whole since the available blood supply for emergency use in other patients is not otherwise depleted.

63. Also, in May 2005 at the ASCO meeting, there was a presentation on a comparative study of Procrit and Aranesp sponsored by Amgen and led by Dr. John Glaspy of the University of California at Los Angeles. The study was designed to find "non-inferiority" of either product if the level of transfusions fell within a broad range. Having defined equivalence in these broad terms, the study concluded that Procrit and Aranesp were not inferior to one another.

64. At the May 2005 meeting, there was a presentation based on an independent, retrospective chart review conducted by Dr. A.S. Case with the University of Alabama at Birmingham. The review was directed at determining the transfusion rates after treatment with Procrit and Aranesp. Based on this observational data, the authors found that a significantly lower proportion of patients required transfusions, and fewer total units were transfused, when treated with Procrit rather than Aranesp.

H. Amgen's Pricing Schemes Have Injured Competition.

65. Amgen's pricing schemes have caused and will continue to cause anti-competitive effects in the relevant product markets. Amgen economically coerces oncology clinics to purchase its RBCGF product, Aranesp, as a condition for receiving substantial price rebates on products that they must purchase from Amgen – WBCGF drugs. Unless they purchase significant amounts of their RBCGF drugs from Amgen, oncology clinics will not qualify for the massive rebates provided on Amgen's dominant WBCGF drugs. Moreover, if they agree to buy virtually all of their RBCGF and WBCGF drugs from Amgen, oncology clinics are given even higher rebates. The only economically viable option for these oncology clinics is to purchase all or nearly all of

their RBCGF drugs from Amgen, even though many physicians would prefer Procrit if Aranesp competed head-to-head with Procrit.

66. Amgen's coercive bundling programs have caused public and private health care insurers to reimburse clinics for their Aranesp purchases at rates that are higher than would have prevailed in "head–to-head" competition.

67. Moreover, Amgen's actions substantially foreclose Ortho from selling Procrit to oncology clinics. This foreclosure is demonstrated by the significant market share shift that has occurred and will continue to occur as a result of Amgen's latest pricing scheme.

68. This anticompetitive foreclosure has caused Ortho to lose revenue and profits that it otherwise would have earned, has disrupted Ortho's relationships with Oncology clinics, and has resulted in loss of good will and other harm to Ortho's ability to innovate and compete.

69. The anticompetitive effects of Amgen's tying and attempts to monopolize extend far beyond the substantial foreclosure of Ortho, which is Amgen's only competitor in the sale of RBCGF drugs. There are numerous other potential uses for epoetin alfa that will likely develop in free and competitive drug markets. Without achieving a reasonable rate of return on current uses of Procrit, Ortho's ability to fund current and future research and development projects related to alternative uses of Procrit and to seek regulatory approvals for these alternative uses is substantially reduced. Ortho's ability to enter new markets with Procrit, either as a first mover or as a challenger to incumbents, is severely undermined by Amgen's tying and attempt to monopolize.

70. Amgen's tying arrangement would also require potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if these potential competitors were as efficient as Amgen. In this manner, Amgen's tying arrangement has caused and will continue to cause anticompetitive effects by increasing the barriers to entry into RBCGF drug markets.

71. In addition, Amgen's conduct enhances and reinforces its monopoly power in the market for WBCGF drugs.

I. Amgen's Pricing Schemes Have Irreparably Harmed Ortho and the Public.

72. Amgen's pricing schemes are intended to foreclose, and have foreclosed, Ortho from a sizeable segment of the oncology clinic market, and will embolden Amgen to take similar action in the hospital market. Amgen's pricing schemes have had a devastating impact on Ortho and on patient care. Ortho has lost important longstanding customer relationships as well as the goodwill built up over the years of the Procrit franchise which has been used to treat millions of cancer patients suffering from the severe anemia that often accompanies chemotherapy. Amgen's actions have also resulted in reductions in investments in ongoing research and development in order to provide better forms of treatment.

73. Eliminating Ortho as an effective competitor in the oncology clinic market results in less physician choice. Physicians and patients should not be effectively cut off from access to the benefits of Procrit – which many physicians would prefer to Aranesp – by virtue of Amgen's use of its monopoly leverage in the sale of WBCGF drugs.

74. If unchecked, Amgen will do the same thing in the hospital market now that hospitals are reimbursed under an ASP system. This will compound the irreparable harm to Ortho and physicians and patients.

J. There is No Legitimate Business Justification for Amgen's Tying Arrangement.

75. There is no legitimate business purpose or efficiency justification for Amgen's pricing schemes. Amgen has employed these schemes for the sole purpose of eliminating Ortho and potential entrants as competitors in the sale of RBCGF drugs to oncology clinics.

K. Sales of RBCGF Drugs to Oncology Clinics Constitute a Relevant Product Market.

76. RBCGF drugs are sold through various channels. The roughly 2,400 oncology clinics in the United States represent the largest market for Procrit and Aranesp, with over $2.8 billion in gross sales projected in 2005. "Oncology clinics" include the small number of "mixed use" clinics that provide oncology as well as other clinic services.

77. To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are often owned and operated by oncologists in private practice, are the preferred venue for patients to receive outpatient administration of RBCGF drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics.

78. Both Amgen and Ortho have historically treated oncology clinics as a distinct market. Amgen and Ortho participate in audits of epoetin alfa sales designed to align dialysis (Epogen) and non-dialysis Procrit sales in accordance with the license. The audit methodology was formulated by Amgen. It treats oncology clinics as a distinct market segment because oncology clinics use RBCGF drugs exclusively to treat anemia associated with non-

dialysis indications. Because the non-dialysis indications belong to Ortho under the PLA, the audit treats all sales to oncology clinics of both parties' brands of epoetin alfa (Epogen or Procrit) as belonging to Ortho.

79. Amgen and Ortho have also recognized oncology clinics as a distinct market in their pricing. The pricing scheme that is the subject of Ortho's Amended Complaint is being offered only to oncology clinics, and Amgen has used this distinction in other pricing programs. For instance, in the past, Amgen offered hospitals 30% "off invoice" discounts for the purchase of Aranesp, but did not offer oncology clinics this favored "off invoice" pricing.

80. An analysis of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than do hospitals.

81. Hospitals cannot buy more RBCGF drugs than they need and "arbitrage" a portion of their purchases by reselling to oncology clinics. It has been a longstanding practice in the pharmaceutical business to have "own use" clauses in sales contracts precluding resale for profit.

82. Government health care programs, such as Medicare, also treat oncology clinics differently than other purchasers. The amount of reimbursement and the formula utilized by the government for oncology clinics are different than that which are used for other industry participants, such as hospitals.

83. Most oncology clinics purchase drugs through entities called "specialty distributors." Specialty distributors deliver oncology drugs, which often require careful handling (e.g., refrigeration), to thousands of oncology clinics. These specialty distributors are licensed to distribute to oncology clinics.

84. Oncology clinics have formed their own Group Purchasing Organizations ("GPO") to negotiate with drug manufacturers. Historically, certain purchasers of pharmaceuticals have benefited from collectively bargaining with drug manufacturers through GPOs. Hospitals, for instance, belong to GPOs. These hospital GPOs generally do not permit oncology clinics to participate. In recent years, oncology clinics began to form specialized GPOs in an effort to achieve lower prices.

85. The sale of RBCGF drugs to oncology clinics is a market recognized by industry and government.

86. There are high barriers to entry in the sale of RBCGF drugs. Foremost are Amgen's exclusive patent rights over epoetin alfa. A market entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, and (2) secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

L. Sales of WBCGF Drugs to Oncology Clinic Constitute a Distinct and Separate Product Market.

87. The sale of WBCGF drugs in the United States is a relevant product market separate and distinct from the sale of RBCGF drugs.

88. WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.

89. Recognizing this, the Federal Trade Commission ("FTC") stated that "the research, development, manufacture and sale of Neutrophil Regeneration Products" (a.k.a. WBCGF drugs) is a "relevant line of commerce" in a Clayton Act §7 administrative Complaint filed against Amgen and the Immunex Corporation.

90. The sale of WBCGF drugs to oncology clinics is a market recognized by industry and government.

91. There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen's WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter these markets, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

M. Amgen Achieved a Monopoly in the Sales of RBCGF Drugs to Oncology Clinics and Currently Maintains this Monopoly.

92. Amgen achieved a monopoly in the sales of RBCGF drugs to oncology clinics through the unlawful and economically coercive conduct of conditioning the receipt of substantial price rebates on the WBCGF drugs that clinics must purchase from Amgen on the purchase of Amgen's RBCGF drug Aranesp. In October 2005, Amgen's market share of sales of RBCGF drugs to oncology clinics was 66% of the market share. Amgen has since increased and maintained its monopoly share in the RBCGF drug market.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

(Per Se and Rule of Reason Unlawful Tying)

93. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 92 with the same force and effect as if here set forth in full.

94. Amgen has engaged in an unlawful contract, combination, conspiracy and agreement in unreasonable restraint of trade and commerce, in violation of Section 1 of the

Sherman Act, 15 U.S.C. §1. This includes agreements with oncology clinics that force them to purchase all or nearly all of their demand for RBCGF drugs from Amgen.

95. The product characteristics, uses and character of demand for RBCGF drugs (which are used to treat chemotherapy-induced anemia but not neutropenia) are different from the product characteristics, uses and the character of demand for WBCGF drugs (products that treat neutropenia, but not anemia). RBCGF and WBCGF drugs are distinct products: they are used to treat different conditions and are not functionally interchangeable.

96. At all times relevant to this action, Amgen has had market power in the sale of WBCGF drugs sufficient to force oncology clinics that purchase WBCGF drugs to also purchase Aranesp regardless of whether these purchasers actually preferred Procrit.

97. A substantial amount of interstate commerce has been and is being affected by Amgen's tying arrangement. The total purchases of RBCGF drugs by oncology clinics was projected to exceed $2.8 billion in 2005.

98. Amgen's tying arrangement forces oncology clinics to purchase all or nearly all of their demand for RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's pricing schemes, which offer significant rebates for the purchase of Amgen's dominant WBCGF drugs if they are purchased in a package with large quantities of Aranesp, the only economically viable option for oncology clinics that need WBCGF drugs increasingly is for them to purchase all or nearly all of their RBCGF drugs from Amgen.

99. Amgen's tying arrangement has substantially foreclosed and will continue to substantially foreclose Ortho from competing with Amgen for the sale of

RBCGF drugs to oncology clinics based on the efficacy of its product and the price of its product on a stand-alone basis. Amgen's pricing scheme has reduced and will continue to reduce the ability of, and incentive for, Ortho to work toward new applications for Procrit for patients who suffer from ailments or diseases not currently treated by Epoetin Alfa.

100. Amgen's tying arrangement has no legitimate business purpose. It achieves no legitimate efficiency benefits and has the anticompetitive effect of foreclosing competition on the merits for the sale of RBCGF drugs to oncology clinics.

101. Amgen's tying arrangement has adversely effected competition in the sale of RBCGF drugs to oncology clinics and will continue to do so unless enjoined.

102. As a result of Amgen's violations of Section 1 of the Sherman Act, Ortho has been injured in its business and property in an amount not presently known, but which is, at a minimum, in excess of one millions dollars, prior to trebling.

103. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

SECOND CLAIM FOR RELIEF

(Attempt to Monopolize RBCGF Drug Market)

104. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 103 with the same force and effect as if here set forth in full.

105. In violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Amgen has willingly, knowingly, intentionally and with specific intent to do so, attempted to monopolize sales of RBCGF drugs to oncology clinics.

106. This attempt to monopolize has been effectuated by a variety of unlawful conduct undertaken with the purpose and effect of eliminating competition in the sale of RBCGF drugs, including but not limited to:

- conditioning the sale of RBCGF drugs on the purchase of WBCGF drugs;
- granting rebates on the sale of WBCGF drugs conditioned upon the purchase of RBCGF drugs from Amgen;
- granting multi-product rebates conditioned upon meeting disguised market share requirements for RBCGF and WBCGF drugs; and
- entering into agreements that have the purpose and effect of requiring customers to purchase all or almost all of their requirements for RBCGF drugs from Defendants.

107. There is, and was at the time Amgen commenced its anticompetitive conduct, a dangerous probability that Amgen, by using these exclusionary practices, will and would monopolize the sale of RBCGF drugs to oncology clinics.

108. Amgen's exclusionary practices have caused and will continue to cause substantial anticompetitive effects on the sale of RBCGF drugs to oncology clinics. Amgen's conduct has substantially foreclosed and will continue to substantially foreclose competition from Ortho in the sale of RBCGF drugs to oncology clinics and other customers. Amgen's conduct has raised and will continue to raise barriers to entry for potential competitors for the sale of RBCGF and WBCGF drugs. Amgen's conduct has also reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit to benefit patients who suffer from ailments or diseases not currently treated with Epoetin Alfa.

109. Amgen intends to take further acts aimed specifically at further foreclosing competition in the sale of RBCGF drugs to oncology clinics.

110. There is no legitimate business justification or pro-competitive benefit from Amgen's exclusionary practices.

111. As a result of Amgen's violations of Section 2, Ortho has been injured in its business and property in an amount not presently known but which is, at a minimum, in excess of one millions dollars prior to trebling.

112. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

THIRD CLAIM FOR RELIEF

(Monopolization of the RBCGF Drug Market)

113. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 112 with the same force and effect as if here set forth in full.

114. In violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Amgen has willingly, knowingly, intentionally and with specific intent to do so, acquired a monopoly of sales of RBCGF drugs to oncology clinics.

115. In violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Amgen has willingly, knowingly, intentionally and with specific intent to do so, maintained a monopoly of sales of RBCGF drugs to oncology clinics.

116. Amgen acquired and is maintaining its monopoly through exclusionary conduct with the purpose and effect of eliminating competition in the sale of RBCGF drugs, including but not limited to:

- conditioning the sale of RBCGF drugs on the purchase of WBCGF drugs;
- granting rebates on the sale of WBCGF drugs conditioned upon the purchase of RBCGF drugs from Defendants;

- granting multi-product rebates conditioned upon meeting disguised market share requirements for RBCGF and WBCGF drugs; and

- entering into agreements that have the purpose and effect of requiring customers to purchase all or almost all of their requirements for RBCGF drugs from Defendants.

117. Amgen's exclusionary practices have caused and will continue to cause substantial anticompetitive effects on the sale of RBCGF drugs to oncology clinics. Amgen's conduct has caused harm to those responsible for ultimately paying for Aranesp administration, including public and private health care insurance plans, and has substantially foreclosed and will continue to substantially foreclose competition from Ortho in the sale of RBCGF drugs to oncology clinics and other customers. Amgen's conduct has raised and will continue to maintain barriers to entry for potential competitors for the sale of RBCGF drugs. Amgen's conduct has also reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit to benefit patients who suffer from ailments or diseases not currently treated with Epoetin Alfa.

118. There is no legitimate business justification or pro-competitive benefit from Amgen's exclusionary practices.

119. As a result of Amgen's violations of Section 2, Ortho has been injured in its business and property in an amount not presently known but which is, at a minimum, in excess of one millions dollars prior to trebling.

120. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Ortho Biotech Products, L.P. respectfully requests the following relief:

A. That the Court declare, adjudge and decree that Amgen has committed the violations of federal law alleged herein;

B. That the Court enter a permanent injunction enjoining Amgen from employing its latest pricing scheme, which began effective October 1, 2005, and any comparable pricing scheme that achieves the same result of coercing oncology clinics to purchase substantial amounts of Aranesp as a condition of access to substantial discounts on Amgen's WBCGF drugs;

C. That Amgen, its directors, officers, employees, agents, successors, and assigns be permanently enjoined and restrained from, in any manner, directly or indirectly conditioning the sale or discounts on the sale of WBCGF drugs on the purchase of RBCGF drugs or any other conduct which has the same purpose or effect, and committing any other violations of Sections 1 and 2 of the Sherman Act described herein and that Amgen, its directors, officers, employees, agents, successors and assigns be enjoined and restrained from, in any manner, directly or indirectly, committing any other violations of the antitrust laws or statutes having a similar purpose or effect; and

D. That the Court award to Plaintiff the damages it has sustained as a result of the illegal conduct of Amgen, in an amount to be proved at trial, to be trebled according to law, plus interest (including prejudgment interest), attorneys' fees and costs of suit, and such other and further relief as this Court may deem just and proper.

JURY DEMAND

Ortho hereby demands trial by jury of all issues properly triable thereby.

Dated: Newark, New Jersey
June 1, 2007

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